IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

EDITH A. HARRIS, Plaintiff, vs. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	4:21-CV-3013 ORDER
JUDY COHEN, Plaintiff, vs. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	4:21-CV-3014 ORDER
CONSTANCE SUNDELL, Plaintiff, vs. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	8:21-CV-32 ORDER

These matters are before the Court on the defendant's three identical motions to certify for interlocutory appeal pursuant to 28 U.S.C. § 1292(b)

(filing 54)[1] issues determined in this Court's Memorandum and Order of September 8, 2021 (filing 51) denying the defendant's motions to dismiss the plaintiffs' amended complaints (filing 33), and for a stay in the proceedings in these actions pending resolution of the appeals. For the reasons that follow, the Court will deny the defendant's motions.

I. STANDARD OF REVIEW

"Permission to allow interlocutory appeals should be granted sparingly and with discrimination." *Union Cty, Iowa v. Piper Jaffray & Co., Inc.*, 525 F.3d 643, 646 (8th Cir. 2008). The movant for certification bears the heavy burden of demonstrating that the case is the exceptional one in which immediate appeal is warranted. *White v. Nix*, 43 F.3d 374, 376 (8th Cir. 1994). It has long been the policy of courts to discourage piece-meal appeals because such appeals often result in additional and unnecessary burdens on the court and litigants. *Union Cty, Iowa*, 525 F.3d at 646. Permission to allow an interlocutory appeal is intended to be used only in the extraordinary cases, where resolution of the appeal might avoid protracted and expensive litigation. *Id.* Section 1292(b) interlocutory appeals are not intended merely to provide review of difficult rulings in hard cases. *Id.*

Section 1292(b) establishes three criteria for certification: The Court must be of the opinion that (1) the order involves a controlling question of law; (2) there is substantial ground for difference of opinion; and (3) certification will materially advance the ultimate termination of the litigation. *White*, 43 F.3d at 377.

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[1] The defendant's motions and briefings are essentially identical in all three cases. The same is true for each plaintiff's response to the defendant's motions. For convenience, except where specifically noted, the Court will cite only to the filings in *Sundell*, case no. 8:21-cv-32.

II. DISCUSSION

The defendant posits three argument for § 1292(b) certification. First, the defendant argues that this Court's conclusion that the plaintiffs' claims were not preempted pursuant to *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001) was "unsupported by any applicable authority." Filing 55 at 2. This Court found *Buckman* to be inapplicable because there, preemption of the respondent's claim was predicated on the express provisions found in the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA). Filing 51 at 6-7. In *Buckman*, the Court concluded, regarding the respondent's claims about the petitioner's fraudulent representations to the FDA about its orthopedic bone screws, that there was "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." 531 U.S. at 352. As such, the respondent's state tort law fraud-on-the-FDA claim was preempted. *Id.*

Here, the plaintiffs' claims have nothing to do with the MDA, or preemption pursuant to the MDA. The plaintiffs' claims concern the defendant's prescription drug, "[a]nd when Congress enacted an express pre-emption provision for medical devices in 1976, it declined to enact such a provision for prescription drugs." *Wyeth v. Levine*, 555 U.S. 555, 567 (2009). Further, this Court found *Buckman* inapplicable because here, the plaintiffs' claims were not fraud-on-the-FDA claims, but failure to warn the consumer claims—claims that "focus on harm that is allegedly perpetrated against consumers rather than the FDA." *Lefaivre v. KV Pharmaceutical Co.*, 636 F.3d 935, 944 (8th Cir. 2011).

The defendant's *Buckman* argument is without merit. The argument fails to identify or address a controlling question of law, or identify a

substantial ground for a difference of opinion regarding the application of *Buckman*.

Next, the defendant argues that the plaintiffs' allegations are insufficient to allege newly acquired information, and that this Court erred in accepting the plaintiffs' "conclusory allegations without analyzing whether the alleged adverse event reports meet the regulatory definition of newly acquired information." Filing 55 at 10-11. The Court disagrees.

The regulations, specifically 21 C.F.R. § 601.12(f)(6), provides that newly acquired information may include, but is not limited to, new clinical studies, reports of adverse events, or new analysis of previously submitted data if the studies, events, or analysis reveal risks of a different type or greater severity or frequency than previously included in submissions to the FDA. Filing 51 at 9-10. This Court identified that the plaintiffs alleged the defendant had received ten adverse event reports before any of the plaintiffs received their first Beovu injection, and as many as twenty-seven adverse event reports before plaintiff Harris' last injection. Filing 51 at 10. The reports concerned patients whose conditions were characterized as serious and resulting in disability. Filing 51 at 5. Further, the plaintiffs alleged that the defendants funded and authored a review of its clinical trial data that was published online before the plaintiffs' Beovu injections, and that this review, according to the plaintiffs, concluded there was a causal connection between Beovu injections and retinal vasculitis. Filing 51 at 10. This is the very kind of information § 601.12(f)(6) identifies as the kind of information *that may constitute* newly acquired information.

The defendant believes that at the Rule 12(b)(6) motion to dismiss stage, the Court should have scrutinized the plaintiffs' allegations to, essentially, see whether there is evidence supporting the plaintiffs' allegations. But that is not

the function of the Court when considering a motion to dismiss under Rule 12(b)(6). The sufficiency of the allegations is examined, not the sufficiency of the evidence in support of the allegations. *Stamm v. Cty. of Cheyenne, Neb.*, 326 F. Supp. 3d 832, 847 (D. Neb. 2018). At this very preliminary stage of the proceedings, it is yet to be seen whether the plaintiffs can marshal evidence to prove that their allegations regarding adverse event reports and the re-evaluation of the defendant's clinical data actually constitutes newly acquired information such that the defendant could unilaterally change its drug label pursuant to the "changes being effected" regulations without FDA approval.

The defendant's argument about the insufficiency of the plaintiffs' newly acquired information allegations is without merit. The defendant's argument fails to identify or address a controlling question of law, or identify a substantial ground for a difference of opinion regarding the sufficiency of the plaintiff's allegations at this very preliminary stage of the proceedings.

Finally, the defendant argues that the Court erred in concluding that preemption is a jury question. Filing 55 at 13. The Court did nothing of the kind. Instead, the defendant has misread the Court's Memorandum and Order. In support of its argument, the defendant cited to page 11 of the Court's Memorandum and Order. Filing 55 at n.40. This cited section of the Court's Memorandum and Order, however, did not address preemption: rather, it addressed the defendant's duty to warn under Nebraska tort law. Filing 51 at 11. The Court had already addressed the issue of preemption beginning at page 10, stating:

> Contrary to the defendant's arguments, *this Court is unable to conclude* that, as a matter of law, the physician-reported adverse event reports, as well as the reanalysis of the defendant's Phase III clinical trial data, does not constitute newly acquired

> information of events or analyses revealing risks different in type or of greater severity than previously reported to the FDA. *The Court is also unable to conclude* that, as a matter of law, even if the physician-reported adverse events and reanalysis of the Phase III clinical trial data were newly acquired information, it was untimely information that failed to trigger the defendant's obligation to adequately warn of the risks and adverse events associated with Beovu injections.

Filing 51 at 10-11.

There is no merit to the defendant's argument predicated on its misreading of the Court's Memorandum and Order.

III. CONCLUSION

The Court finds that the defendant has not identified a controlling question of law in the Court's Memorandum and Order of September 8, 2021, (filing 51), as to which there is substantial ground for difference of opinion, such that an immediate appeal from this Court's order may materially advance the ultimate termination of the litigation. This Court previously considered only whether these three plaintiffs' amended complaints stated plausible claims for relief—nothing more than that. At this very preliminary stage of the proceedings, this matter is not an exceptional case where an immediate appeal is warranted. An interlocutory appeal now, where the issues are not yet fully joined, the defendant has not entered any denials or assertions of avoidances and affirmative defenses, and where no evidence has been produced, would promote piecemeal litigation, and impose unnecessary burdens on the litigants, as well as on this and other courts.

IT IS ORDERED:

1. The defendant's motions to certify issues for interlocutory appeal and for oral argument (case no. 4:21-cv-3013 filing 56, case no. 4:21-cv-3014 filing 55, case no. 8:21-cv-32 filing 54) are denied.

2. The plaintiff's motions for leave to file sur-reply briefs (case no. 4:21-cv-3013 filing 67, case no. 4:21-cv-3014 filing 66, case no. 8:21-cv-32 filing 64) are denied as moot.

Dated this 24th day of November 2021.

BY THE COURT:

John M. Gerrard
United States District Judge